K002339

AUG 2 4 2001

SECTION 12: SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is being submitted in a accordance with the requirements of SMDA 1990 and CFR 807.92.

12.1 SUBMITIER INFORMATION

a. Company Name: APEX MEDICAL CO..

b. Company Address: 10th FL., No. 31, Lane 169, Kang-Ning ST. His-Chin, Taipei Hsien, Taiwan.

c. Company Phone: 886-2-26954122
Company Facsimile: 886-2-26954123

d. Contact Person: Daniel Lee

e. Date Summary Prepared: July 26,2000

12.2 DEVICE IDENTIFICATION

Trade/Proprietary Name: Electrical Muscle Stimulator AEMS V (EMS 1000), and AEMS VI (EMS 1000 plus)

Classification Name: Physical Medicine
21 CFR 890.5890

12.3 IDENTIFICATION OF PREDICATE DEVICE

Company	Device	510(k) No.	Date Cleared
Skylark Device Co., Ltd.	EMS400	K912642	12/09/91

12.4 DEVICE DESCRIPTION

The APEX AEMS V and AMES VI come equipped with a contraction and relaxation time setting and can be operated in different frequency and ramp setting mode. The AEMS V and AEMS VI also equipped with independent output power volume adjustment.

12.5 SUBSTANTIAL EQUIVALENCE

The APEX AEMS V and AEMS VI are substantially equivalent to the EMS 400 in commercial distribution by Skylark.

The fundamental technical characteristics of the APEX AEMS V and AEMS VI are similar to the predicate device and are listed on the comparison charts provided in the 510(k) submission. The APEX AEMS V and AEMS VI and the predicate device function in the ramp, frequency setting. There are relaxation, contraction time setting capabilities with the APEX AEMS V and AEMS VI and the predicate devices. Output power adjustment features are present in all units.

12.6 INTENDED USE

The APEX MEDICAL CORP. Electronic Muscle Stimulator AEMS V and AEMS VI are intended for use in:

1. Relaxation of Muscle Spasm
2. Prevention or retardation of disuse atrophy
3. Increase local blood circulation
4. Muscle re-education.
5. Immediate post surgical stimulation of calf muscles to prevent venous thrombosis.
6. Maintaining or increasing range of motion.

This device is restricted to sale or used by or on the order of a physician licensed in the state in which he or she is practicing.

12.7 TECHNOLOGICL CHARACTERISTICS

A comparison of the technological characteristics of the APEX AEMS V and AEMS VI with the predicate device is provided within this submission. They are composed of a main unit, output control, leadwires and electrode. Both adjustable power outputs are available with the APEX AEMS V and AEMS VI and the predicate devices. Ramp and frequency setting are also common to each of the units.

12.8 PERFORMANCE DATA

The APEX AEMS V and AEMS VI were subjected to performance bench testing in accordance with applicable industry and clinical standards. Physical performance studies were conducted to verify that the testing in accordance with applicable industry and clinical standards. Physical performance studies were conducted to verify that the APEX AEMS V and AEMS VI conformed to all emission and immunity standards in accordance with EN and IEC regulations. Results of the testing showed that the APEX AEMS V and AEMS VI perform as intended.

12.9 510(k) CHCKLIST

This notification contains all information required by 21 CFR 807.87.A completed copy of the Premarket Notification 510(k) Reviewer's Checklist is provided in this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 4 2001

Mr. Daniel Lee, President
Apex Medical Corp.
10th Fl., No. 31, Lane 169, Kang Ning St.
His Chih Chen, Taipei Hsien, 221, Taiwan, R.O.C.

Re: K002339
Trade/Device Name: AEMS V (EMS 1000) and AEMS VI (EMS 1000 PLUS)
Regulation Number: 21 CFR 890.5850
Regulatory Class: II
Product Codes: IPF
Dated: May 24, 2001
Received: May 29, 2001

Dear Mr. Lee:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response

to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE

510(k) Number : K002339

Device Name: APEX Electronic Muscle Stimulator AEMS V (EMS-1000), AEMS VI (EMS-1000 PLUS)

Indication for Use: The APEX MEDICAL CORP. Electronic Muscle Stimulator AEMS V, VI is intended for use in:

1. Relaxation of Muscle Spasm.
2. Prevention or retardation of disuse atrophy.
3. Increase local blood circulation.
4. Muscle re-education.
5. Immediate post surgical stimulation of calf muscles to prevent venous thrombosis.
6. Maintaining or increasing range of motion.

This device is restricted to sale or used by or on the order of a physician licensed in the state in which he or she is practicing.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhoan

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K002339

Prescription Use X OR ~~Over-The-Counter Use~~

(Per 21 CFR 801.109)